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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/866,793

Filing Date: May 30, 2001

Appellant(s): VESPER, STEPHEN JOSEPH

Anne M. Kornbau

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2-27-06 appealing from the Office action mailed 4-8-05.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

Appellant's brief presents arguments relating to the objection to the specification at page 19. This issue relates to petitionable subject matter under 37 CFR 1.181 and not to appealable subject matter. See MPEP § 1002 and § 1201.

(7) Claims Appendix

A substantially correct copy of appealed claims 23-33 appears on page 21-23 of the Appendix to the appellant's brief. The minor errors are as follows: the withdrawn claims (34-38) have been included in the claim appendix.

(8) Evidence Relied Upon

6,210,670	Berg	04-2001

Bendayan J. Histochem. Cytochem. 43:881-886, 1995.

Bost et al. Immunology Invest. 17:577-586, 1988.

Ebina et al Japanese Journal of Medical Science and Biology 53(3):140, 1982.

Ebina et al Japanese Journal of Mecical Mycology 39(2):155-160, 1997.

Harlow et al "Antibodies A Laboratory Manual", Cold Spring Harbor Press Inc., 1989, pages 390-393.

Sakaguchi et al . Japanese Journal of Medical Mycology, 25(3):Abstract, 1984.

Watanabe et al., Journal of Tohoku Pharmaceutical University, 46:145-148, 1999 abstract.

Yakota et al, Microbiology and Immunology, 21(1):11-22, 1997.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 23 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakaguchi et al (Japanese Journal of Medical Mycology, 25(3):Abstract, 1984) in view of Harlow et al (Antibodies A Laboratory Manual, Cold Spring Harbor Press, 1989, pages 390-393).

The claims are drawn to a method for determining if an animal has been exposed to a hemolysin-producing fungus comprising contacting a sample from the mammal with labeled antibodies that bind to hemolysin produced by the fungus and detecting any complex formed by the labeled antibodies and the hemolysin.

Sakaguchi et al teach the immunohistochemical detection of the secretion of Asp-hemolysin in tissues (i.e. the instant sample) from a mouse infected with *Aspergillus fumigatus* (i.e. the instant mammal). Sakaguchi et al specifically teach "An attempt was made to detect the fungi and the production of hemolysis in various tissues during the infection. Toxins dyed blue were actually detected in the kidneys and brain. In mice inoculated with 10^7 spores via the coccygeal vein, the production and secretion of toxins were detected after two days on the periphery of the fungi in the renal cortex and cerebrum. In mice still alive two weeks after inoculation with 5×10^6 spores, the presence of toxins dyed blue on the periphery of fungi was confirmed in the glomerular tissue and some urinary tubes of the kidneys (Fig. 2). These results were similar to the

ones reported by Iwada et al.11 indicating that the growth of *A. fumigatus* was most prevalent in the kidneys and brain in experimental fungal infections.

Using the indirect immunoenzymatic method, the production and secretion of hemolysin were actually confirmed in an infected organism." The immunohistochemical method uses and indirect enzyme labeled peroxidase binding IgG antibody (see English Abstract). The method differs by labeling the second or indirect antibody, rather than the primary or binding antibody.

Harlow et al teaches that in immunohistochemical techniques the antibodies can be labeled directly. Harlow et al teach that both the direct and indirect methods are in common use and that the labeling of the primary or binding antibody provides for the advantage of cleaner signals with lower background (see page 390, first full paragraph). Further, Harlow et al teaches that the labeled primary antibodies may be labeled with enzymes, fluorochromes or iodine (see page 392, section 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time that the invention was made to modify the immunohistochemical assay for the detection of Asp-hemolysin in a mammalian sample because Harlow et al teaches that labeled primary antibody provides for the advantage of cleaner signals with lower background and that both the direct and indirect methods are in common usage. It would have also been *prima facie* obvious to substitute the enzyme label in the method as combined supra for any other appropriate label according to Harlow et al (fluorochromes or iodine) to label the primary antibody for detection of the Asp-hemolysin because Harlow et al teach that these are conventional alternative labels for a labeled primary antibody for histochemistry.

Claim 33 is rejected under 35 U.S.C. 102(b) as being anticipated by Sakaguchi et al (Japanese Journal of Medical Mycology, 25(3):Abstract, 1984).

The claim is drawn to a method for determining if an animal has been exposed to a specific hemolysin-producing fungus comprising detecting the presence of the hemolysin produced by the fungus in a sample from the animal, the presence of the hemolysin in the sample indicating that the animal has been exposed to the hemolysin producing fungus.

Sakaguchi et al teach the immunohistochemical detection of the secretion of Asp-hemolysin in tissues (i.e. the instant sample) from a mouse (i.e. the instant animal) infected with hemolysin producing *Aspergillus fumigatus* (i.e. the instant hemolysin-producing fungus). The immunohistochemical method uses an indirect enzyme labeled peroxidase binding IgG antibody. Sakaguchi et al specifically teach "An attempt was made to detect the fungi and the production of hemolysis in various tissues during the infection. Toxins dyed blue were actually detected in the kidneys and brain. In mice inoculated with 10^7 spores via the coccygeal vein, the production and secretion of toxins were detected after two days on the periphery of the fungi in the renal cortex and cerebrum. In mice still alive two weeks after inoculation with 5×10^6 spores, the presence of toxins dyed blue on the periphery of fungi was confirmed in the glomerular tissue and some urinary tubes of the kidneys (Fig. 2). These results were similar to the ones reported by Iwada et al.11 indicating that the growth of A. fumigatus was most prevalent in the kidneys and brain in experimental fungal infections. Using the indirect immunoenzymatic method, the production and secretion of hemolysin were actually confirmed in an infected organism. As such, the method of Sakaguchi et al determines if the animal has been exposed to hemolysin-producing fungus by detection of the hemolysin in renal cortex and cerebrum of mice (i.e. the instant animal). Sakaguchi et al teach that the production and secretion of hemolysin were actually confirmed in an infected organism (mouse). As such, Sakaguchi et al anticipates the instantly claimed invention because it determines infection by detection and secretion of hemolysin from the hemolysin-producing fungus *Aspergillus fumigatus*. The mice were exposed to the hemolysin producing fungus *Aspergillus fumigatus* and the exposure was detected by detection of

hemolysin in samples from the mice. Sakaguchi et al inherently anticipate the claimed invention. *Ex parte Novitski* 26 USPQ 1389 (BPAI 1993); *Mehl/Biophile International Corp. V. Milgraum*, 52 USPQ2d 1303 (Fed. Cir. 1999); *Atlas Powder Co. V. IRECO*, 51 USPQ2d 1943 (Fed. Cir. 1999). The mouse was exposed to a hemolysin-producing fungus and the hemolysin was detected in tissues using an immunohistochemical method. As such, the presence of hemolysin in the tissue sample is a *de facto* marker of exposure to *Aspergillus fumigatus* hemolysin. (Rejection of record in Office Action of 7-14-04)

Claims 23-29 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Appellant argues that the limitation of "a specific hemolysin-producing fungus" is meant and intended to be read as "species specific". First, the specification lacks basis for claiming "a specific hemolysin-producing fungus" and Appellant has not pointed to the specification by page and line number where written description support for this claim language can be found. Further, the there is no conception or written description of any hemolysin being species-specific. The species-specificity of hemolysins is not discussed in the specification, there is no comparison of hemolysins of different Fungal genera, much less any discussion of different species within the same genera nor the ability of any antibody to discriminate between them. The specification fails to provide written description support for the phrase "specific hemolysin-producing fungus" and clearly fails to provide for conception of using hemolysins to distinguish different species within the same genera as argued.

Claims 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for determining if a building contains a hemolysin-producing fungus comprising, obtaining a sample from the building, contacting the sample with labeled antibodies and detecting any complex formed between the labeled antibodies and the fungal hemolysin or active fragments of the hemolysin. The specification at paragraphs [0018] and [0036] teach screening of buildings for hemolysin-producing fungi. In these passages, a strain of fungus is obtained from the building is grown in a synthetic medium at a suitable incubation temperature and a culture filtrate is applied to a 5% sheep blood agar plate. If the filtrate is shown to be hemolytic, the strain is problematic and may pose a health risk. These passages of the specification do not provide for the concept of contacting a building sample with a labeled antibody to detect the hemolysin. This issue is best resolved by Appellant specifically pointing to the passage in the specification where the now claimed method has written description support. It is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977). (Rejection of record in Office Action of 7-14-04)

Claims 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method for determining if a building contains a hemolysin-producing fungus comprising, obtaining a sample from the building, contacting the sample with labeled antibodies and detecting any complex formed between the labeled antibodies and the fungal hemolysin or active fragments of the hemolysin. The specification at paragraph [0025] indicates that growing *S. chartarum* in trytpic soy broth in an incubator at 36±1° provides for a culture supernatant comprising fungal hemolysin. The specification fails to teach that the fungal hemolysin is present on the outside of spores or conidia as are conventionally found in buildings, such that a labeled antibody would bind. The presence of detectable hemolysin in a non-cultured environmental sample has not been tested nor contemplated by the specification. The specification fails to teach that the hemolysin is directly detectable in an environmental sample. There is no evidence in the art of any fungal spore or conidia having detectable hemolysin on its surface. While the art teaches detection of bacterial spores using spore-specific antibodies and particular immunological methods, this specification does not teach that the hemolysin is readily available on the spore or conidia coat. The specification fails to teach that the presence of fungal-hemolysin can be detected in a crude building sample in the absence of broth culture. As such, one skilled in the art would have to determine if the hemolysin was present on the surface of the fungal spores or conidia before any assessment of the presence or absence in a building sample could begin. Further, even if the spore surface had the hemolysin present, it is unclear if the method as claim is sensitive enough to detect the levels present in a crude building sample. Even the specification teaches that a strain must be isolated, liquid cultured and the culture supernatant tested on sheep blood agar. The courts have held that the disclosure is insufficient when testing is necessary to determine the actual use or possible lack of use. *(In re Kirk and Petrow* (CCPA) 153 USPQ 48). In the absence of further guidance by Appellant, the specification as filed fails to enable the detection of a hemolysin-producing fungus by the claimed method (Rejection of record in Office Action of 7-14-04).

Claims 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended in the preamble to recite "which hemolysin is species-specific". There is no conception by way of written description in the specification as filed for species-specific hemolysins. There is no inherent or implicit showing using evidence of specificity on the part of hemolysins. There is no evidence of comparison of hemolysins from different fungi or different species within the same genus that conveys to the skilled artisan that Appellant had conceived that the hemolysin per se or antibodies thereto was species specific. The issue of specificity has been addressed fully above with respect to claims 23-39 and 33 as set forth above and in the previous office action of record. None of the relied upon passages cited and argued by Appellant conveys the concept of species-specificity or specificity related to using individual hemolysins as diagnostic. The reference to detecting strains producing hemolysins does not convey support for differentiating genera and/or species on the basis of detection of hemolysin.

Claims 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 30 and dependent claims 31 and 32, the claim preamble is drawn to a method for determining if a building contains a hemolysin-producing fungus, however step (b) recites "obtaining hemolysin from the sample if hemolysin-producing fungi are present in the sample". This method step requires that one know that hemolysin is present. As

such, what is the objective of the method ? If you obtain hemolysin from the sample under the conditions if hemolysin-producing fungi are present in the sample, then you already know that hemolysin-producing fungus is in the sample. Therefore, the sample is not an unknown but a known, that is known to have hemolysin. As such, the method step (b) is contrary to measuring an unknown, where the presence or absence of a hemolysin is unknown. Step (b) requires that you know that the hemolysin is present. What is the purpose of performing the assay.

(10) Response to Argument

Claims 23 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakaguchi et al (Japanese Journal of Medical Mycology, 25(3):Abstract, 1984) in view of Harlow et al (Antibodies A Laboratory Manual, Cold Spring Harbor Press, 1989, pages 390-393).

Appellant argues that the inventors have discovered the hemolysin producing fungi produce hemolysins that are specific to each fungus. This is not persuasive, because every protein is specific for the cell from which it is derived. Further this is not persuasive because the specification as filed does not convey the concept of discrimination of fungi based on the structure or function of the hemolysin. No data is presented demonstrating that the hemolysins known in the art and that newly set forth in this specification for *Stachybotyrus* are structurally distinct by known biochemical or immunological parameters (i.e. antibodies that bind one hemolysin do not bind the others). The specification does not demonstrate that antibody assays, such as that claimed, are able to discriminate between different species of Stachybotryus much less discriminate among the different genera or species of fungi producing hemolysins. This concept is simply not conveyed by the specification as filed. In contrast to Appellant's assertion, it was known in the art that hemolysins were produced by specific fungi and antibodies could be used to detect the fungi that produced the hemolysins. The *Aspergillus* and Candida

species that produced the hemolysins could be specifically detected by detection of the hemolysins. Further, the specific structure of the *Aspergillus fumigatus* toxin detected by Sakaguchi et al was known to the art (Ebina et al, 1997) and was not identified by the art as being produced by other microorganisms at the time of the invention. Appellant argues certain fungi produce hemolysins which are particular to the particular fungus producing the hemolysin and it is noted that specific fungi produce hemolysins which could be used to detect the specific fungi producing them is not new to the art in view of Sakaguchi et al herein. Appellant argues species -specificity and strains. Appellant interchangeably misuses the terms species and strains. Fungi are conventionally called by the Genus, species, and strain. For example, *Aspergillus fumigatus AH1*. Appellants rely upon [0015] "It is a further object of the present invention to identify strains of fungi using an *in vitro* test." It is maintained that strains are not species and a teaching for a strain is not a teaching for a species. Different species can belong to the same (*Stachybotyrus*) or different genera (*Aspergillus* or *Candida*). As such, Appellant's arguments for inherency of the concept is misplaced because an assay that identifies different strains of the same genus/species of fungi that produce the hemolysin is not a teaching that each of the strains produce a unique hemolysin and cannot be inherently extended to species discrimination within or outside the genus as apparently argued by Appellant. It merely demonstrates that one can distinguish the toxogenic or hemolysin producing strains of *Stachybotyrus chartarum* from those that do not produce the toxin and nothing more. This concept is provided in the specification at [0018]. The discrimination of strains that produce hemolysin versus strains that do not produce hemolysin says nothing about the ability of the hemolysin to discriminate between different species of hemolysin producing *Stachybotyrus* or different genera such as *Aspergillus* or *Candida*. The art term of "species" does not equal "strains". Appellants argue that the examiner appears to be confusing antibody specificity with hemolysin specificity. This is not persuasive. The assay must be specific, the antibodies are by

definition specific for the specific hemolysin to which they are generated. Antibody specificity is not equated in the art with a lack of cross-reactivity. Appellants previously argued in their response the antibodies are specific. Appellants argue paragraph [0024] of the specification which teaches "By growing strains of hemolysin producing fungi *in vitro* and isolating the hemolysin, it is not possible to use the protein to identify fungi which are isolated from buildings, homes, schools, and the like. The fungal strains are grown in a conventional synthetic medium such as tryptic soy broth, at about 37oC." The position of the office is that the prior art necessarily performed the same method to produce the *Aspergillus fumigatus* antibody that bound the hemolysin produced thereby and therefore necessarily detects strains producing the *Aspergillus fumigatus* hemolysin. This is the same method performed in the specification. Appellant again argue that if each fungus did not produce a species-specific hemolysin, it would be impossible to identify which fungi are present. The art merely provides as much information as the specification in either of [0015] or [0050], teachings directed to strains and not different species or genera. An antibody was raised to the *Aspergillus fumigatus* hemolysin and the antibody was used to detect in tissue the hemolysin in an experimentally induced infection with the same genus/species. Thus, the prior art of Sakaguchi et al teach strain detection of the *Aspergillus fumigatus* hemolysin. The teachings of the art are the same as that of the specification. Make an antibody and detect the hemolysin using the antibody. The reagents and methods of the prior art are the same methods as taught by the specification. Harlow et al was not cited for a method of producing antibodies as asserted by Appellant but provides for the teaching that "..... in immunohistochemical techniques the antibodies can be labeled directly. Harlow et al teach that both the direct and indirect methods are in common use and that the labeling of the primary or binding antibody provides for the advantage of cleaner signals with lower background (see page 390, first full paragraph). Appellant completely misses the statement in the rejection of record of the missing teaching "The method differs by

labeling the second or indirect antibody, rather than the primary or binding antibody." Harlow et al was cited to teach that the labeled primary antibodies may be labeled with enzymes, fluorochromes or iodine (see page 392, section 2)." Appellant queries how the examiner can extend deliberate infection to an assay that does not involve taking a tissue sample. This is not persuasive, the claims are not so limited. All that is required by the method is two active steps, contacting a sample from the animal with a labeled antibody and detecting complex formation between an hemolysin and the antibody. The claims as drafted are not seen to exclude either deliberate exposure to experimental animals, deliberate exposure by biological warfare agent release or unknown exposure. The claims as currently drafted encompass any sample and do not exclude tissue samples. Until Sakaguchi et al it was unknown if the hemolysin would be produced *in vivo*. Sakaguchi et al teach that the hemolysin from a hemolysin producing strain is produced *in vivo* and can be detected in tissue samples therefore. So at the time of the assay it was unknown if one could determine hemolysin production *in vivo*. It was an unknown at the time Sakaguchi et al made the inquiry. Sakaguchi et al teach that the hemolysin produced could be detected in a tissue sample from an animal infected with the fungus to which the antibody was raised. Appellant misdirect to the intentions of "Sakaguchi et al". Appellants argue that there is nothing in the references as combined that would lead one of skill in the art to measure if the animal was exposed to a particular hemolysin-producing fungus. This is not persuasive, the claims merely require for determining if an animal has been exposed to a specific hemolysin, that the exposure of the art is deliberate does not obviate that the method of the prior art detects exposure (i.e. deliberate) by detection of the *Aspergillus fumigatus* toxin in a sample. The rat of the art was exposed to a known hemolysin producing strain of *Aspergillus fumigatus*, exposure was detected using detection of hemolysin in tissue samples. Thus, the art indicates that exposure to a hemolysin producing strain of *Aspergillus fumigatus* could be and was detected in experimental infection by detection of asp-hemolysin from *Aspergillus fumigatus* in tissue samples using

antibodies that bind the asp-hemolysin. The "intentions" of Sakaguchi et al are not pertinent because they are not pertinent to the relied upon teachings in the art rejection. Appellants again argue discrimination of genus/species/strain, a concept that is not set forth either in the specification or the body of the method as drafted. By logical assumption and in view of the specific teaching for *Stachybotryus chartarum* in the specification, a hemolysin that is derived from a cell is a specific marker for that cell, because this is all that the specification shows. That does not mean that the protein has the ability to discriminate between different cells as argued by Appellants. Therefore, it is maintained that the assay of Sakaguchi et al specifically identifies the specific hemolysin from the specific hemolysin producing fungus, *Aspergillus fumigatus*. This interpretation of specificity has basis in the specification because it is exactly what was performed for the *Stachybotyrus chartarum* hemolysin. Appellant argues *Manning v. Paradis*, 269 F3d 1098, 1103; 63 USPQ2d 1681 (Fed. Cir. 2002) wherein the court adjudicated that "Just as the preamble of a count may define a limitation of the count, so too it may define the intended purpose of the invention." Whether a preamble stating the purpose and context of the invention constitutes a limitation of the claimed process is determined on the facts of each case in light of the overall form of the claim, and the invention as described in the specification and illuminated in the prosecution history. In the instant case the preamble is not limiting because "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997). In the instant case, absent the preamble, one would be able to perform the method steps and therefore the body of the claim is structurally and functionally complete. In summary, the art teaches that the *Aspergillus fumigatus* hemolysin can be specifically detected in a sample from an animal infected therewith. This animal is by definition exposed to the fungus, because it is infected. That the exposure is deliberate does not distinguish between the methods as set forth in the body

of the claims. *Aspergillus fumigatus* is a known pathogen that infects humans (Ebina et al, Japanese Journal of Medical Mycology, 39(2):155-160, 1997, see page 158, Table 2 and Table 3, in particular). The antibody raised against the asp-hemolysin specifically binds and detects the hemolysin. This is the same methodology used by Appellant for the disclosed *Stachybotryus chartarum* hemolysin. Since the specification and the art use the same methodology to produce the antibody (i.e. raised against the hemolysin from a particular genus and species of fungus), the method using an antibody made by this process is by definition, innately species-specific. An antibody raised against an antigen will by definition specifically bind that antigen. As previously set forth, the existence of specific fungal hemolysins produced by specific fungi were known and in fact, known well prior to the filing date of this application (asp-hemolysin: Yakota et al , Microbiology and Immunology, 21(1):11-22, 1977, Ebina et al, Japanese Journal of Medical Science and Biology, 53(3):140, 1982; *Candida alb cans* hemolysin (Watanabe et al , Journal of Tohoku Pharmaceutical University, 46(145-148, 1999 abstract). Appellants arguments that specific-hemolysin producing fungi were not known is inconsistent with the art of record. In conclusion, it is the position of the office, that the combination of art meets the method steps of the body of the claim when species specificity and specific-hemolysin are interpreted in view of the specific teachings of the specification for *Stachybotyrus chartarum*.

Claim 33 is rejected under 35 U.S.C. 102(b) as being anticipated by Sakaguchi et al (Japanese Journal of Medical Mycology, 25(3):Abstract, 1984).

It is noted that the argued rejection is incorrectly titled by Appellants at page 10 of the brief as a rejection under 103(a). The rejection on appeal is correctly set forth at page 5 of the brief and herein as a rejection under 102(b). The claim recites a single step "detecting the presence of the hemolysin produced by the fungus in a sample from the animal, the presence of the hemolysin in the sample indicating that the animal has been

exposed to the hemolysin-producing fungus." The method of the prior art meets the single step method. As such, the prior art anticipates the instantly claimed invention. Appellant again argues specificity and the preamble of the claims. All of Appellant's arguments for specificity are not persuasive for reasons set forth for the 103 rejection directly above and are not reiterated herein for brevity. Appellant's arguments regarding limitations in the preamble of the claim in regard to "if exposed" is not seen to exclude deliberate infection in an animal model or deliberate infection by biological agents as set forth directly above. The intention or purpose of the invention as set forth in the preamble is not seen as limiting for reasons set forth directly above. The prior art performs the method step of the instant claim. The functions of the reagents are inherent properties of the biological agents. Appellant again argues the intent of the research of Sakaguchi et al is different and they did not intend to detect exposure but were studying the effects of toxin. This is not persuasive. Sakaguchi et al practiced the method as claimed. Exposure of the animals to a hemolysin producing fungus was detected using antibodies that bound the hemolysin in an animal sample. It is noted that the preamble of the claim is past tense and as such the rats were in fact "exposed". There is not one method step of the art that is different from that as claimed and therefore the method of the prior art anticipates the claimed invention. The research intent does not obviate the fact that Sakaguchi et al practiced the claimed invention. Appellant argues that Sakaguchi et al knew that the animals were exposed to a hemolysin producing fungus. This is not persuasive; the animals of the prior art were "exposed". The claims require detection of exposure, the fact that the exposure was deliberate does not obviate the fact that exposure to a hemolysin fungus was detected by detection of hemolysin in tissue samples. Appellants argue that there is no recognition that a specific hemolysin could be used to identify each specific fungus. This is not persuasive; the method would inherently do so. The mice were exposed to the hemolysin producing fungus *Aspergillus fumigatus* and the exposure was detected by detection of hemolysin produced

by the *Aspergillus fumigatus* fungus in tissue samples from the mice. Sakaguchi et al inherently anticipate the claimed invention. *Ex parte Novitski* 26 USPQ 1389 (BPAI 1993); *Mehl/Biophile International Corp. V. Milgraum*, 52 USPQ2d 1303 (Fed. Cir. 1999); *Atlas Powder Co. V. IRECO*, 51 USPQ2d 1943 (Fed. Cir. 1999). The mouse was exposed to a hemolysin-producing fungus and the hemolysin was detected in tissues using an immunohistochemical method. As such, the presence of hemolysin in the tissue sample is a *de facto* marker of exposure to *Aspergillus fumigatus* hemolysin. Appellant argues that nothing-in Sakaguchi et al even suggest that hemolysin-specific fungi produce individual hemolysins. This is simply false. Sakaguchi et al teach that the specific fungus *Aspergillus fumigatus* produces an individual hemolysin. As previously set forth, the existence of fungal hemolysins produced by specific fungi were known and in fact, known well prior to the filing date of this application (asp-hemolysin: Yakota et al , Microbiology and Immunology, 21(1):11-22, 1977, Ebina et al, Japanese Journal of Medical Science and Biology, 53(3):140, 1982; *Candida albicans* hemolysin (Watanabe et al , Journal of Tohoku Pharmaceutical University, 46(145-148, 1999 abstract).

Claims 23-29 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The issue is that the phrase "a specific hemolysin-producing fungus" is meant and intended to be read as "species-specific" discrimination of fungi. It is noted that Appellant has shifted their argument from that of the response filed 2-15-05 as citing a new section of the specification, however the issue remains the same and the new paragraph is substantially the same as that previously argued. Previously Appellant argued paragraphs [0012], [0013] and [0024]. The traversal of the previous arguments are placed

in context of Appellants reliance on [0012], [0015] and [0032] herein. Appellant amended the claims to recite "which hemolysin is species specific" in the response of 2-15-05. As set forth in the Office Action of 4-8-05, "the specification as filed lacks conception of "species specificity" and the ability to discriminate one fungus from another based on species-specific hemolysin. Appellant points to [0012] and [0013] that state "It is an object of the present invention to provide a method and reagent for screening humans and other animals for exposure to hemolysin-producing fungi" and "It is another object of the present invention to provide a method and reagent for screening humans and other animals for exposure to *Stachybotyrus chartarum*." respectively. These passages do not convey the concept of species-specific hemolysin or hemolysins that are species specific. Screening methods do not have to discriminate between genera or species of fungus. There is no discussion of the specificity of the hemolysin for discrimination between exposures to different fungi or the specificity of the hemolysin to discriminate between different fungi. There is no data in the specification that functionally supports Appellant's assertions that these paragraphs provide for conception by way of written description that would indicate that species-specific hemolysins were produced and these hemolysins were able to discriminate between the genus and species of different hemolysin-producing fungi. Reliance on paragraph [0015] which only stated "It is a further object of the present invention to identify strains of fungi using an *in vitro* test" is not dispositive of the issue for reasons set forth above. The actual disclosure indicates that antibodies raised to the hemolysin can be used to detect strains (not different species; not different genera) of *S. chartarum* that produce the hemolysin (see [0032]). There is no discussion of the ability of the fungal hemolysin to discriminate between different species or different genera. Appellant previously argued that [0024] supports discrimination. This is not persuasive; the discussion is limited to determining if strains of the same genus and species produce the hemolysin. Strains of a fungus such as *S. chartarum* are not equivalent to different species of fungus (i.e. *S. atra*) and are not

equivalent to different genera (i.e. *Aspergillus; Candida*) There is no data in the specification that supports Appellant's allegation that the contemplated screening assay was able to discriminate between the contemplated Genus and species of fungi. Detection of strains of a particular genus/species of *S. chartarum* does not support genus or species discrimination or specificity of the hemolysin to discriminate among such. Appellant improperly argues hemolysin-producing strains to mean species. Appellant argues that one skilled in the art cannot identify strains unless there is a distinct marker for each fungus. This concept/idea is not set forth in the specification. Further, one can distinguish strains of a fungus producing a hemolysin without having a specific marker, because the genus/species have particular biochemical and growth characteristics that distinguish it from other species. The strains of a particular genus/species of fungi that produce hemolysin are readily distinguished from the other strains of the same genus/species that do not on the basis of detection of production of the hemolysin. This says nothing about the ability of the hemolysin to discriminate between different species of *Stachybotyrus* nor different genera such as *Aspergillus* or *Candida*. Appellant argues that passage [0030] means that the antibodies can detect exposure to a hemolysin producing fungus such as *S. chartarum*. The term specific as it relates to antibodies is conventionally set forth in the art to reference the ability of the antibody combining site to bind the cognate structure on the antigen (i.e. hemolysin). The term specific binding or specific for an antigen does not convey the concept as exclusive binding (i.e. non-cross reactive). As evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586) and Bendayan (J. Histochem. Cytochem. 1995; 43:881-886) is known in the art that an antibody "cross-reacts", i.e., binds to more than one protein sequence, does not mean that the antibody does not "specifically react" with both proteins. For example, Bost et al. describe antibodies which "cross-react" with IL-2 and HIV envelope protein, but establish that the binding of each protein is due to the presence of a homologous sequence in each protein in which 4 of 6 residues were identical (see entire document, but especially the Abstract and Discussion). Antibodies which bound

either the HIV or IL-2 derived sequence did not cross react with irrelevant peptides (e.g., "Results, page 579). Similarly, Bendayan characterizes the specific reactivity of a monoclonal antibody produced to human proinsulin and shows that although the antibody is highly specific; it is nevertheless able to bind to not only human proinsulin, but to proinsulin from other species and even a distinct protein, glucagon, based upon conservation of an Arg-Arg dipeptide sequence in each of these molecules (see entire document). Bendayan concludes that "an antibody directed against such a sequence, although still yielding specific labeling, could reveal different molecules not related to the original antigen" (page 886, last paragraph). See also U.S. Pat. No. 6210670 (Berg) entitled "Cross-Reacting Monoclonal Antibodies Specific for E-Selectin and P-selectin". Appellant's argument attempts to limit the term "specifically reacts" in a manner inconsistent with the well-known and art-recognized specificity of antibody interaction with epitopes defined by particular amino acid sequences. Consequently, it was well known in the art at the time the invention was made that antibody binding of distinct proteins was indeed specific and therefore the passage does not convey to the art that *the antibody bound exclusively* to the hemolysin from *Stachybotyrus chartarum* and not to any other fungal hemolysin as asserted. Any antibody raised to any antigen binds it specifically, this term does not imply that the binding is exclusive or unique. For the foregoing reasons the written description of the specification does not convey the concept for either the asserted "specific hemolysin-producing fungus" or the now recited "hemolysin is species-specific". Further, the specification provides no evidence of any lack of cross-reactivity for multiple hemolysins from different genera/species/strains such that an antibody raised to one hemolysin would not bind to a hemolysin from the others. Antibodies raised to an antigen (hemolysin) are by definition specific for that antigen (hemolysin), however, specificity used in the context of antigen binding, clearly without more, does not provide for the concept of discrimination between antigens. This concept of antibody "specificity" as inherently defining an antibody as not cross-reactive is clearly

incorrect set forth by the references of record. Appellants argue that paragraph [0032] indicates that clearly antibodies to fungal hemolysin can be used in conventional immunoassay to determine if one has been exposed to strains of fungi that produce hemolysin. Again it is the position of the office that this paragraph does not convey discrimination between different hemolysins using antibodies. The passage sets forth nothing more than what the art already knew, (Yakota et al , Microbiology and Immunology, 21(1):11-22, 1977, Ebina et al, Japanese Journal of Medical Science and Biology, 53(3):140, 1982; *Candida albicans* hemolysin (Watanabe et al , Journal of Tohoku Pharmaceutical University, 46(145-148, 1999 abstract)) that hemolysin-producing fungi could be detected using immunoassays. Appellants now argue paragraph [0015] which states that "It is a further object of the invention to identify strains of fungi using an in vitro test.". This passage requires further interpretation by Appellant who clearly expounds on the teaching of the specification by inferring that that the test involves determining the presence of that hemolysin to infection by the fungus that produce the hemolysin as a means of discrimination between fungi. This interpretation appears nowhere in this specification as filed. Strains are not species, which in turn are not genera. Appellants are inappropriately simply mixing and matching terms that have particular meaning in the art and inferring teachings that would not be clear and unambiguous or logically flow therefrom to the skilled artisan. As such, the skilled artisan would not confuse strains with species with genera. Watanabe et al, Journal of Tohoku Pharmaceutical University, 46:145-148, 1999 abstract, clearly provide for the concept of strains and that strains differ in the ability to produce fungus-specific-hemolysins. Appellant further interpretation, above that which is explicitly set forth in the specification as filed, flies in the face of strain discrimination as opposed to species discrimination. That strains varied in their ability to produce hemolysin was know to the art as shown by Watanabe et al of record. Therefore the differentiation of fungal species producing the hemolysin does not and can not be inferred from or logically flow from passage [0015]. Appellant argues that if species

discrimination were not set forth in the specification, then the invention would be inoperable. The position on operability of the invention is not an issue of record, nor has it been raised previously in the record by the examiner. Appellant again argues that humans do not produce normal antibodies in response and therefore traditional methods to detect exposure cannot be used. This files in the face of years of development of immunoassays to detect bacterial hemolysin and fungal hemolysin *in vitro*. Traditional immunoassays for exposure to microorganisms provide for detection of antigen or antibody. The assay as claimed is in fact a traditional immunoassay. Appellant on page 12 reiterates the invention but provides no argument. Appellant argues *In re Gosteli*, 872 F2d 1008, 1012, 10 USPQ 1614, 1618 (Fe. Cir. 1989) provides that the written description requirement merely provides the persons of ordinary skill in the art to recognize that which is claimed. It is respectfully submitted, that given the evidence and argument of record that the skilled artisan could not find the concept of discrimination of species based on unique hemolysins. The specification simply does not provide any intrinsic evidence of unique hemolysin by structural or immunological characterization. Appellant clearly misuses strain discrimination for species discrimination. Clearly the skilled artisans, a microbiologist and an immunologist, familiar with antibody specificity and immunological techniques would not confuse strains with species. These two terms have precise meanings to the microbiologist, antibody specificity has precise meaning to the immunologist and the combination of both does not lead to species discrimination. Appellants at page 13, last paragraph merely reiterate the teachings of the specification. These teachings are conventional assay teachings and do not convey the concept of species or strain specificity, nor discrimination of one from the other on the basis of specific hemolysins as claimed. These teachings are what the art of record teaches and nothing more. As such, it is maintained that the concept of species-specific, or discrimination or one species from another, is not conveyed to the skilled artisan by the relied upon teachings of the specification as filed. The hemolysin(s) of the art and the hemolysin of *Stachybotyrus*

chartarum have not been demonstrated to be structurally, functionally or immunologically distinct in the specification as filed. As such, the concept of discrimination of species based on presence of hemolysin has not been conveyed to the skilled artisan. The teachings of the specification are no more than that which is performed by the art of record which is isolation of the hemolysin, making an antibody, detection of the hemolysin produced by the fungus from which is was isolated by using the antibody raised to it. None of this conveys species specificity or hemolysin specificity, as are the argued meaning of these terms.

Claims 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The issue is whether the method steps of the claim have conception by way of written description in the specification as originally filed. Appellant has argued that it is perfectly clear to one skilled in this particular art, where the skill is relatively high, one would expect that one skilled in the art could readily extrapolate, without undue experimentation, a method for detecting the fungi isolated from a building suspected of containing the hemolysin-producing fungi. Appellant asserts that it is clear that Appellant has invented this invention. This is not persuasive. Appellant is reminded that the claimed invention is not defined by mere broad sweeping concepts, but the specific method steps of the claims. The entirety of the teachings of the specification for methods of detecting hemolysins in buildings is set forth in paragraph [0036]. Paragraph [0036] clearly sets forth for the skilled artisan, the methods to determine if a building holds fungi which are problematic, at the time that the invention was made. This method is quite distinct from the methods set forth in claims 30-32. The method of the specification provides for "...a

strain of a fungus obtained from the building is grown in a synthetic medium such as tryptic soy broth at a temperature which the fungus can be made to grow, generally about 37oC. The culture filtrate is then applied to a plate, such as 5% sheep red blood cell agar plate. If the filtrate is shown to be hemolytic the strain is problematic and may pose a health risk." It is completely unclear how this method as contemplated by Appellants at the time of filing used to determine if a building holds a fungi that is problematic, i.e. produce hemolysin can be extrapolated to the instantly claimed method. Appellants previously argued that paragraphs [0025]-[0033] set forth provide a method for detecting the hemolysin using antibodies. This is not persuasive, the relied upon passages are directed to determination of exposure and detection of antibodies as a means of determining exposure in an animal or human. These passages never mention the use of the immunoassay in context of determining if a building contains a hemolysin-producing fungus or specific-hemolysin producing fungus. There is no written description in these passages that conveys the concept that the immunoassay is useful in screening buildings for the hemolysin producing fungi. There is no conception of using the assay, Appellants are mixing and matching different concepts to attempt to find support for the method as is now claimed. Appellants appeared to admit in the response of 2-15-05 that the assay is not expressly contemplated by instead arguing that the skilled artisan would need to extrapolate the teachings of the specification because the skilled artisan would know how to assay. The passages of the specification as previously argued by Appellant do not convey the concept of the claimed method steps as set forth in claims 30-32 for use in the detection of hemolysin-producing fungi in a building at the time the invention was made. Methods and concepts must either be explicitly disclosed or logically flow from specific passages of the specification to demonstrate that the inventor had possession of the claimed invention, not just the preamble, at the time of filing. The claimed invention includes the method steps not just the concept in the preamble. In the instant case, the concept of detection in a building is explicitly set forth at the time of filing at paragraph

[0036] in the specification. This method cannot be logically extended to the instantly claimed method steps. It is noted that entitlement to a filing date does not extend to subject matter that is not disclosed, but would be obvious over what is expressly disclosed. *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961 (Fed. Cir. 1977).

Claims 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Appellant's arguments do not address the rejection and comments of record. Appellants again rely upon the skilled artisan to know how to assay and not the functionality of the assay as claimed. The issue here is practicing the claimed method steps to achieve the goal of the preamble. As previously set forth, Appellants have amended the claim in the response of 2-15-05 to recite a new method step of obtaining hemolysin from the sample if hemolysin-producing fungi are present in the sample. However, the method still contacts "the sample" with the labeled antibodies. There is no relationship between step (b) as now recited and the antibodies of step (c). Further, the specification does not teach how to obtain hemolysin from the building sample *per se*. Appellant argues that the claims have been amended to recite that the sample is cultured and that any hemolysin-producing fungus will produce the hemolysin, that then can be detected. This is not persuasive; there is no culturing step. There is a step of obtaining hemolysin from the sample. There is no positively culturing step and Appellant's arguments are inconsistent with the text of the amendment. Appellants newly rely and argue that one skilled in the art would know how to obtain samples and then as described in paragraphs [0025]-[0032] assay for the presence of hemolysin. This is not persuasive. The claims require that the hemolysin be obtained from the building sample. The specification does not teach how to obtain hemolysin from a building sample. Appellants

argue that paragraph [0036] which pertains specifically to screening fungi in a building, even discloses a culturing technique. The claims do not have a culturing step or filtrate used from the culturing step and the method of paragraph [0036] start with a strain of fungus obtained from the building and NOT an sample from the building. The claims merely require obtaining the hemolysin from the building sample. There are no process steps disclosed in the specification that provide for obtaining hemolysin directly from a building sample. One of skill in the art would not know how to process the building sample to obtain hemolysin therefrom. The claims do not require strain isolation and culturing but obtaining the hemolysin from "the sample". The antecedent basis of the claim does not provide for intermediate strain isolation and culturing steps. The hemolysin must be obtained from the sample from the building. The strain isolation and culturing technique is not set forth in the claims. Further, the obtained hemolysin is never contacted with the labeled antibodies. As such, the method steps are neither described nor enabled for the determining if a building contains a hemolysin-producing fungus for reasons made of record as set forth supra. The issue set forth is that the presence of detectable hemolysin in a non-cultured environmental sample has not been tested nor contemplated by the specification. The specification fails to teach that the hemolysin is directly detectable in an environmental sample. The method requires this direct detection because the sample in (a) is in (c) contacted with the labeled antibodies. There is no evidence in the art of any fungal spore or conidia having detectable hemolysin on its surface. While the art teaches detection of bacterial spores using spore-specific antibodies and particular immunological methods, this specification does not teach that the hemolysin is readily available on the spore or conidia coat. The specification fails to teach that the presence of fungal-hemolysin can be detected in a crude building sample in the absence of isolation of fungal strains and broth culture. As such, one skilled in the art would have to determine if the hemolysin was present on the surface of the fungal spores or conidia before any assessment of the presence or absence in a building sample could begin.

Further, even if the spore surface had the hemolysin present, it is unclear if the method as claim is sensitive enough to detect the levels present in a crude building sample. Even the specification teaches that a strain must be at least isolated, liquid cultured and the culture supernatant tested on sheep blood agar. The courts have held that the disclosure is insufficient when testing is necessary to determine the actual use or possible lack of use *(In re Kirk and Petrow* (CCPA) 153 USPQ 48). In the absence of further guidance by Appellant, the specification as filed fails to enable the detection of a hemolysin-producing fungus by the claimed method. The standard under 112, 1st paragraph and requires Appellant describing in sufficient detail of how to make and use their invention. The specification lacks description of direct detection of hemolysin in building samples. The claim must be enabled as set forth. The contrivance of the skill artisan to insert necessary and required steps to practice the claimed invention appears to admit that the method and concept as specifically set forth in the claimed method steps is insufficiently described in the specification as filed, insufficiently claimed and not enabled.

Claims 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The issue is whether or not the phrase "which hemolysin is species-specific" as recited in the claims is new matter. Appellants assert that it is well understood by those skilled in the art reading the present specification that hemolysin-producing fungi produce hemolysins that are sufficiently specific for each fungus so that one skilled in the art can differentiate among such. This is not persuasive, the specification does not even use the term differentiate, does not demonstrate specificity of the hemolysins either by structure or function and there is no inherent or implicit evidence of specificity on the

part of hemolysins in the specification as filed. There is no evidence of structural or functional comparison of hemolysins from different fungi or different species within the same genus that conveys to the skilled artisan that Appellants had conceived that the hemolysin *per se* could be used to distinguished fungi from each other (i.e. the instant species specific) using methods or antibodies contemplated in the specification. Appellant argues that it is clear from the teachings of the specification as filed, that the hemolysins were species specific. This is not persuasive because there is no comparative data which one skilled in the art would have then immediately envisioned species-specificity as an inherent disclosure. The only disclosure in the specification is for a single hemolysin from the fungi *Stachybotyrus chartarum*. There is no comparison of the structure of this hemolysin as compared to others that are admittedly known in the art. Further, since all are hemolysins (i.e. hemolize blood), the inherent function of the protein does not distinguish a hemolysin from one fungus as opposed to a different fungus. Appellant relies upon case law that provides for later amending the claims and specification to provide for an inherent function or an advantage of a device disclosed (*Technicon Instruments Corporation v Coleman Instruments, Inc. et al* 255 F.Supp. 630, 150 USPQ 277 (N.D. Ill. 1966), aff'd 385 F.2d 391, 155 USPQ 369 (7th Cit. 1967). First, it is noted that species-specificity is a characteristic of the hemolysin *per se* and is not a reagent in the assay performed. The assay performed uses a reagent that is not the hemolysin *per se*. Therefore, the additional functional information with respect to the species specificity of the fungal hemolysin is not an inherent characteristic of the assay reagent. Second, it is noted that Appellant has provided no extrinsic evidence that the hemolysin the specification has the asserted inherent function. As set previously set forth, the specification as originally filed provides no intrinsic evidence in the specification as originally filed that would allow the skilled artisan to immediately envision that hemolysins could be used to discriminate species of fungi. Finally, assertions of counsel are insufficient to establish inherency of a method, the assertion of "one skilled in the art

would know" is insufficient to provide written description or establish inherency of the later claimed functionality. Appellant relies upon *In re Kirchner* et al, 49 C.C.P.A. 1234, 305 F.2d 897, 904, 134 USPQ (BNA) 324, 330 (CCPA 1962) to indicate that the invention may be described in different ways and still be the same invention. This is not persuasive; the insertion of a new concept not previously provided for in the specification is not a different description of an invention, but an invention that was not conceived of at the time of filing. Different descriptions of the same invention are by claiming a protein by either its structure, function or structure and function. By analogy in a method, one would claim the method by claiming different methods of detection or different steps. The instant claims are not claiming the same invention in a different way, they are claiming an invention for which the specification at the time of filing has no written description support and as such Appellant was not in possession of the later claimed invention. Appellant also relies upon *In re Nathan*, 51 C.C.P.A. 1059, 328 F.2d 1005, 1008-09, 140 USPQ (BNA) 601, 604 (CCPA 1964) wherein a later added limitation was found to be an inherent characteristic of the claimed subject matter. The instant case is differentiated from such, because the later claimed characteristic has not been demonstrated to be an inherent characteristic. It cannot be said that it is clear from reading the specification that hemolysin-producing fungi produce hemolysin that is species specific so that individual fungi can be identified. There is no written description in the specification that the skilled artisan would point to for which they could immediately envision that discrimination between fungi was a contemplated concept at the time of filing. As such, the skilled artisan, in the absence of discriminatory data or written description of structural characteristics of the hemolysins from different fungi showing that they were sufficiently unique so that antibodies raised to the individual hemolysins could distinguish between the fungi could not readily appreciate the inserted "which hemolysin is species specific" was a conveyed at the time of filing.

Claims 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Appellant argues that you obtain hemolysin *if* hemolysin-producing fungi are present in the sample. The method requires obtaining hemolysin from the sample and Appellant indicates that the step (b) does not require that the person knows that hemolysin is in the sample in view of the word "if" present and the preamble which also indicates determining "if" a building contains a hemolysin-producing fungi. This is not persuasive; in order to obtain hemolysin, one would have to know that the sample contains hemolysin. The step requires "obtaining hemolysin from the sample". What does this step mean if hemolysin-producing fungi are not in the sample ? This step has no meaning in context of the claimed method if one skilled does not know whether or not the sample contains hemolysin-producing fungi. The skilled artisan can only obtain hemolysin "if" they know that hemolysin-producing fungi are present in the sample. Appellant argues that that if one already knows hemolysin-producing fungi are in the building what is the purpose of assaying for it ? This is not the issue. The issue is that the claim as drafted makes no sense unless the person already knows that the fungi present produce hemolysin. The step in context of an unknown and in context of the claim makes no sense. Appellants argue that if there are not hemolysin-producing fungi in the building, one could not obtain hemolysin-producing fungi from the sample. This is not what the claim says. The method step of the claim is not obtaining hemolysin-producing fungi from the sample. The method step is obtaining hemolysin from the sample. If hemolysin-producing fungi are not present in the sample, what does this step mean ? Appellant argues that if hemolysin-producing fungi are present, one recovers hemolysin from the sample and assays it to determine what hemolysin-producing fungi are present in the building. This is not what the method steps of the claims indicate. The claims as set forth assay the sample.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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